

**Wyeth Consumer Healthcare**

Five Giralda Farms  
Madison, NJ 07940

**Lauren Quinn JD**

Director  
Regulatory Affairs  
973.660.6167  
quinnL4@wyeth.com

**Wyeth**

November 16, 2006

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Room 1061 (HFA-305)  
Rockville, MD, 20852

**RE: OTC Monograph for Nasal Decongestant Drug Products  
Docket 76N-052N**

Dear Sir or Madam:

Reference is made to a recent series of communications between Representative Waxman and the FDA on the efficacy of 10 mg phenylephrine. As a result of these communications, Wyeth Consumer Healthcare (WCH) has reviewed its records and is submitting information on three unpublished studies conducted between 1967 and 1983 that were not previously submitted to the OTC Monograph for Nasal Decongestant Drug Products, Docket 76N-052N. Accompanying the study reports is a review of the data supplied to the docket, as well as a review of the literature from 1976 to the present.

After reviewing the data, WCH concurs with the Agency opinion that at a dose of 10mg, phenylephrine is a safe and efficacious oral nasal decongestant.

Sincerely,



WYETH CONSUMER HEALTHCARE

Lauren Quinn, JD  
Director, Regulatory Affairs

cc: C. Ganley, Office of Nonprescription Drug Products

enc.